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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,616	01/22/2004	Luisa Hernandez-Ramirez	91349	5023

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EXAMINER	
HUYNH, CARLIC K	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/762,616	HERNANDEZ-RAMIREZ ET AL.	
	Examiner	Art Unit	
	Carlic K. Huynh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *7-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 13-22* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *18 September 2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks filed on July 23, 2007 is acknowledged.

Status of the Claims

1. Claims 1-22 are pending in the application, with claims 7-12 having been withdrawn from consideration, in response to the restriction requirement submitted on December 26, 2006. New claims 13-22 have been added in applicants' amendments and remarks filed on July 23, 2007. Accordingly, claims 1-6 and 13-22 are being examined on the merits herein.

Information Disclosure Statement

The Information Disclosure Statement submitted on September 18, 2007 is acknowledged.

Response to Arguments

2. Applicant's amendments, see "Remarks" filed on July 23, 2007, with respect to "IN THE SPECIFICATION" have been fully considered and are found persuasive. The Applicants have amended the specification by: (1) adding a comma in "parasitic infections, urinary or fecal incontinence" on page 2, line 7; (2) changing to "fluconazole-tinidazole association" in tables associated with each of examples 1-3; and (3) changing to "either tinidazole or secnidazole is used" in line 6 of the abstract. Thus the "Objections to the Specification" are withdrawn in light of the amendments.

3. Applicant's amendments, see "Remarks" filed on July 23, 2007, with respect to "Claim Objections" have been fully considered and are found persuasive. The Applicants have amended claims 1 and 3 to reflect the correct spelling of fluconazole. Thus the "Claims Objections" are withdrawn in light of the amendments.

4. Applicant's arguments, see "Remarks" filed on July 23, 2007, with respect to "Rejections under 35 U.S.C. § 112, second paragraph" to claim 1 have been fully considered and are found persuasive. Claim 1 has been amended to "stereoisomer" and "stereoisomeric". Thus the "Rejections under 35 U.S.C. § 112, second paragraph" to claim 1 has been withdrawn.

5. Applicant's arguments, see "Remarks" filed on July 23, 2007, with respect to "Rejections under 35 U.S.C. § 112, second paragraph" to claim 3 have been fully considered and are found persuasive. The percent by weight of fluconazole in claim 3 has been amended to "6% ± 2%". Thus the "Rejections under 35 U.S.C. § 112, second paragraph" to claim 3 has been withdrawn.

6. Applicant's arguments, see "Remarks" filed on July 23, 2007, with respect to "Rejections under 35 U.S.C. § 103" to claims 1-3 have been fully considered and are found persuasive in part. Applicants have argued that Lin et al. does not teach oral administration but rather teach

topical administration. Although Lin et al. teach topical administration, this argument is not found persuasive because claims 1-3 do not have the limitation of oral administration.

Applicants have also argued that Lin et al. does not provide specific combinations of fluconazole and tinidazole or fluconazole and secnidazole. This argument is not found persuasive because Lin et al. states "The compositions of this invention may have active ingredient is selected form the following: an antifungal compound, an antibacterial compound, a moisturizing compound, an antiviral compound and the like or a combination thereof" (page 2, paragraph [0016]). This statement provides enough evidence that the composition of Lin et al. may comprise of two antifungal compounds, either fluconazole and tinidazole or fluconazole and secnidazole.

Applicants have further argued that Lin et al. do not teach "50 to 150 mg of fluconazole" but rather "at least 400 mg of fluconazole". This argument has been found persuasive because Lin et al. do not teach "50 to 150 mg of fluconazole" but rather "at least 400 mg of fluconazole". Thus, the "Rejections under 35 U.S.C. § 103" to claims 1-3 have been withdrawn in light of the argument.

7. Applicant's arguments, see "Remarks" filed on July 23, 2007, with respect to "Rejections under 35 U.S.C. § 103" to claims 4-6 have been fully considered and are found persuasive. Applicants have argued that Lin et al. do not teach "50 to 150 mg of fluconazole" but rather "at least 400 mg of fluconazole" and that Eichman teach a drug resin complex and that the drug resin complex does not contain "suggestion or motivation to combine the antifungal and antiamebic compounds in a drug resin complex". This argument is found persuasive because Lin et al. do not teach "50 to 150 mg of fluconazole" but rather "at least 400 mg of fluconazole" and

Eichman does not teach a "suggestion or motivation to combine the antifungal and antiamebic compounds in a drug resin complex". Thus, the "Rejections under 35 U.S.C. § 103" to claims 4-6 have been withdrawn in light of the argument.

8. Applicant's arguments with respect to claims 1-6 have been considered but are moot in view of the new ground(s) of rejection. The following new ground(s) of rejection to amended claims 1-6 and 13-22 are used herewith.

Claim Objections

9. Claim 1 is objected to because of the following informalities: typographical errors. Fluconazole is misspelled in claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-6 and 13-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 2003/0236236).

Chen et al. teach a combination of active agents, fluconazole and secnidazole or fluconaole and tinidzole (page 3, paragraph [0037]; and pages 4-7, paragraph [0045]). The active agent is present up to 50% in a fine dispersion (page 3, paragraph [0035]). The dosage form of the pharmaceutical composition may comprise a tablet (page 8, paragraph [0061]). The

pharmaceutical composition contains solubilizers, surfactants, and additives according to methods well known in the art (page 8, paragraph [0058]). Thus, it would be obvious that the composition of Chen et al. contain acceptable pharmaceutical vehicles such as microcrystalline cellulose, sodium glycolate of starch, polyvinylpyrrolidone, magnesium stearate and white opadry as recited in claims 6 and 16.

Regarding the mg amount of fluconazole and tinidazole in the pharmaceutical composition as recited in instant claims 1 and 21, Chen et al. teach the active agent is present up to 50% in a fine dispersion (page 3, paragraph [0035]), which meets the limitations of the instant claims. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the quantity of fluconazole and tinidazole provided in a composition, according to the guidance set forth in Chen et al., to provide a composition having the desired weight of fluconazole and tinidazole in the pharmaceutical composition. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding the % by weight of fluconazole and tinidazole in the pharmaceutical composition as recited in instant claims 13, 17, and 19, Chen et al. teach the active agent is present up to 50% in a fine dispersion (page 3, paragraph [0035]), which meets the limitations of the instant claims. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the % by weight of the fluconazole and tinidazole provided in a composition, according to the guidance set forth in Chen et al., to provide a composition having the desired % by weight of fluconazole and

tinidazole in the pharmaceutical composition. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding the mg amount of fluconazole and secnidazole in the pharmaceutical composition as recited in instant claims 2 and 22, Chen et al. teach the active agent is present up to 50% in a fine dispersion (page 3, paragraph [0035]), which meets the limitations of the instant claims. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the quantity of fluconazole and secnidazole provided in a composition, according to the guidance set forth in Chen et al., to provide a composition having the desired weight of fluconazole and secnidazole in the pharmaceutical composition. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding the % by weight of fluconazole and secnidazole in the pharmaceutical composition as recited in instant claims 3, 18 and 20, Chen et al. teach the active agent is present up to 50% in a fine dispersion (page 3, paragraph [0035]), which meets the limitations of the instant claims. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the % by weight of fluconazole and secnidazole provided in a composition, according to the guidance set forth in Chen et al., to provide a composition having the desired % by weight of fluconazole and secnidazole in the pharmaceutical composition. It is noted that "[W]here the general conditions of a claim are

disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

11. Claims 1, 13-17, 19, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Compton et al. (US 2003/0059471).

Compton et al. teach a combination of drugs, fluconazole and tinidazole (page 4, paragraph [0043]; page 14, paragraph [0142]; and page 18, paragraph [0173]). The drugs are from about 0.01 to 1000 mg/kg per day (page 27, paragraph [0312]). The compositions are suitable for oral administration and may be presented as tablets (page 27, paragraph [0315]). The compositions also contain salts, buffering agents, preservatives, and compatible carriers (page 26, paragraph [0305]). Thus, it would be obvious that the composition of Compton et al. contain acceptable pharmaceutical vehicles such as microcrystalline cellulose, sodium glycolate of starch, polyvinylpyrrolidone, magnesium stearate and white opadry as recited in claims 6 and 16.

Regarding the amount in mg of fluconazole and tinidazole in the pharmaceutical composition as recited in instant claims 2 and 22, Compton et al. teach drugs are from about 0.01 to 1000 mg/kg per day (page 27, paragraph [0312]), which meets the limitations of the instant claims. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the quantity of fluconazole and tinidazole provided in a composition, according to the guidance set forth in Compton et al., to provide a composition having the desired weight of fluconazole and tinidazole in the pharmaceutical composition. It is noted that "[W]here the general conditions of a claim are disclosed in the prior

art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding % by weight of fluconazole and tinidazole as recited in instant claims 3, 18 and 20, Compton et al. teach drugs are from about 0.01 to 1000 mg/kg per day (page 27, paragraph [0312]), which meets the limitations of the instant claims. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the % by weight of fluconazole and tinidazole provided in a composition, according to the guidance set forth in Compton et al., to provide a composition having the desired % by weight of fluconazole and tinidazole in the pharmaceutical composition. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Conclusion

12. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh

SHENGJUN WANG
PRIMARY EXAMINER